

Applicant: Jerzy A. Georgiades  
Serial No. 09/719,944  
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such that the trademarks SMA<sup>TM</sup> and WHITE<sup>TM</sup> are now capitalized. No new matter has been added to the application.

***Claim Rejections - 35 U.S.C. §112***

Also in the prior Office Action, the Examiner rejected claims 3 and 4 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner noted that there was insufficient antecedent basis for the limitation in claim 3 that begins "the selenium". By this Amendment, claim 3 has been amended to depend from claim 2, rather than claim 1. There is clearly now sufficient antecedent basis for the limitation in claim 3 that begins "the selenium".

Reconsideration of the rejection of claim 3 is respectfully requested.

The Examiner rejected claim 4 as being indefinite and ambiguous for recitation of "tissue necrosis factor". Applicant notes that "tissue necrosis factor  $\alpha$ " is actually recited in claim 4. Tissue necrosis factor  $\alpha$  is a well-known member of the interferon family, as is noted on page 5, lines 4-8 of the specification. Thus, recitation of "tissue necrosis factor  $\alpha$ " in claim 4 is not indefinite, novel, or confusing, and would readily be understood by one of ordinary skill in the art. In light of the foregoing clarification, reconsideration of the rejection of claim 4 is respectfully requested.

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***Claim Rejections - 35 U.S.C. §102***

In the prior Office Action, the Examiner rejected claim 1 under 35 U.S.C. §102(b) as being anticipated by Cockrum, GB 2,289,278 (Immuno-Dynamics Inc.). The Cockrum, GB 2,289,278 (Immuno-Dynamics Inc.) reference describes a dietary supplement that includes dried colostral powder.

By this Amendment, applicant has amended claim 1 to specify that the dietary supplement comprises *purified* colostrinin. This amendment to claim 1 clearly adds no new matter to the application (support for the amendment to claim 1 can be found on page 4, line 19).

Applicant submits that the amendment to claim 1 clearly differentiates the dietary supplement as claimed in claim 1 in the present application from the dietary supplement disclosed in the Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) reference. The Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) reference clearly does not disclose, teach or suggest a dietary supplement comprising *purified* colostrinin as claimed. Dried colostral powder, while containing some colostrinin, is not the same as *purified* colostrinin, as claimed.

Applicant notes that the Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) reference was cited and considered during prosecution of application from which the present application claims priority, namely Georgiades, GB 2,354,153 (ReGen Biotech Limited). Claim 1 of the present application, as amended, is now identical to claim 1 of

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the priority application, which was allowed over the Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) reference (see copies of GB 2,354,153 bibliography and Status Information attached hereto). Reconsideration of the rejection of claim 1 is respectfully requested.

***Claim Rejections - 35 U.S.C. §103***

The Examiner rejected claims 2-4 under 35 U.S.C. §103(a) as being unpatentable over Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) as applied to claim 1 further in view of Janusz et al., WO 98/14473, Adler et al., WO 97/43905, Hiroto et al., JP 2,265,458 (Nikken Food KK), and Inglot et al., 1996 Arch. Immunologiae et Therapiae Experimentalis, Vol. 44, pp. 215-224. Applicant notes that only Janusz et al., WO 98/14473, discloses purified colostrinin, but this reference does not disclose, teach or suggest a dietary supplement comprising purified colostrinin in combination with lactoferrin and/or selenium. There is no teaching in Janusz et al., WO 98/14473, nor in the other cited references, whereby one of skill in the art would be motivated to create a dietary supplement comprising purified colostrin in combination with lactoferrin and/or selenium. Accordingly, the rejection of claims 2-4 under 35 U.S.C. §103(a) is clearly improper. Reconsideration of the rejection is respectfully requested.

Claims 7 and 8 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cockrum, GB 2,298,278 (Immuno-Dynamics Inc.) as applied to claim 1 further in view of Plaut et al., WO 97/05884 (New England Medical Center Hospital) and Adler et

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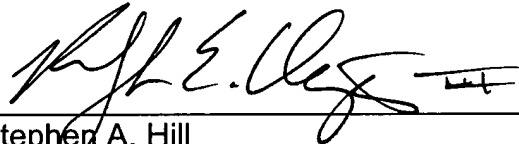
al., WO 97/43905. None of the references cited against claims 7 and 8 discloses, teaches or suggests a baby food formulay comprising a dietary supplement comprising *purified* colostrinin in combination with lactoferrin. The rejection of claims 7 and 8 is therefore improper. Reconsideration of the rejection is respectfully requested.

### CONCLUSION

In light of the foregoing, it is submitted that the application is presently in condition for allowance, and a notice to that effect is therefore earnestly solicited.

Respectfully submitted,

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**ATTACHMENT A**  
**(Version Showing Changes Made)**

***In the Specification:***

The paragraph beginning on page 8, line 3, was amended as follows:

A formulation for feeding to a baby post weaning from mother's milk, is:

Proprietary milk powder

(e.g. [~~Sma<sup>TM</sup>~~, ~~White<sup>TM</sup>~~] SMA<sup>TM</sup>, WHITE<sup>TM</sup> by Sma

Nutrition, Maidenhead, U.K. \*) 4g \*\*

Natural ovine colostrinin 150µg

Selenium (bound to

lactobacilius acidophilus) 8.25µg (free selenium)

Human Recombinant Lactoferrin 1.0 mg

- \* [~~Sma<sup>TM</sup>~~] SMA<sup>TM</sup> ingredients quoted as lactose, skimmed milk powder, vegetable oils, emulsifier (soy lecithin), potassium bicarbonate, vitamin C, taurine, ferrous sulfate, zinc sulfate, cytidine-5'-monophosphate, disodium uridine-5'-monophosphate, vitamin E adenosin-5'-monophosphate, niacin, disodium inosine-5'-monophosphate, disodium guanosine-5'-

monophosphate, pantothenic acid, vitamin A, copper sulphate, thiamin, vitamin B, riboflavin, beta-carotene, manganese sulphate, folic acid, vitamin K, potassium iodide, biotin, vitamin D, vitamin B. Although the manufacturer lists ferrous sulphate as an ingredient, we prefer not to include this material or any other iron containing compounds.

- \*\* Follow manufacturer's instructions for dosage guide e.g. weight 6.5 kg, approximate age of baby 4 months, 7 level scoops in 200 ml cooled (freshly boiled) water.

***In the Claims:***

Claims 1 and 3 were amended to read as follows:

1. (AMENDED) A dietary supplement comprising purified colostrinin in combination with lactoferrin.
3. (AMENDED) A dietary supplement according to claim [4] 2, wherein the selenium is in the form of a physiologically acceptable selenoprotein.

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A23C 9/20 , A23L 1/305 , A61K 35/20

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(56) Documents Cited by ISA

GB 2289278 A WO 98/14473 A WO 97/43905 A  
WO 97/05884 A

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(54) Abstract Title

**Dietary supplement**

(57) A dietary supplement comprises a combination of colostrinin and at least one of lactoferrin and selenium.

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CLAIMS

1. A dietary supplement comprising purified colostrinin in combination with lactoferrin.
2. A dietary supplement according to claim 1, further comprising selenium.
3. A dietary supplement according to claim 1, wherein the selenium is in the form of a physiologically acceptable selenoprotein.
4. A dietary supplement according to claim 1, further comprising at least one cytokine selected from interferon  $\alpha$ , interferon  $\gamma$ , interleukin 1- $\alpha$ , interleukin 1-3, interleukin 6, 8, 10, 12, 16, tissue necrosis factor  $\alpha$ , G-CSF, M-CSF, TGF $\alpha$  and TGF $\beta$ .
5. A dietary supplement comprising purified colostrinin in combination with selenium.
6. A dietary supplement comprising colostrinin in combination with at least one cytokine selected from interferon  $\alpha$ , interferon  $\gamma$ , interleukin 1- $\alpha$ , interleukin 1-3, interleukin 6, 8, 10, 12, 16, tissue necrosis factor  $\alpha$ , G-CSF, M-CSF, TGF $\alpha$  and TGF $\beta$ .
7. A baby food formula comprising a dietary supplement according to any preceding claim.
8. The use of dietary supplement according to any preceding claim in a baby food formula.
9. A tablet lozenge or other solid oral dosage form comprising 12.5 micrograms to 200 micrograms purified colostrinin, 10 micrograms to 100 milligrams lactoferrin, and 2.5 to 100 micrograms seleno-cysteine in combination with a physiologically acceptable carrier.



10. The use of purified colostrinin in combination with lactoferin in the manufacture of a medicament for improving the immune system of mammals.

11. The use of purified colostrinin in combination with selenium in the manufacture of a medicament for improving the immune system of mammals.

12. The use of purified colostrinin in combination with at least one cytokine selected from interferon  $\alpha$ , interferon  $\gamma$ , interleukin 1- $\alpha$ , interleukin 1-3, interleukin 6, 8, 10, 12, 16, tissue necrosis factor  $\alpha$ , G-CSF, M-CSF, TGF $\alpha$  and TGF $\beta$  in the manufacture of a medicament for improving the immune system of mammals.



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REGISTER ENTRY FOR GB2354153

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Title DIETARY SUPPLEMENT

Applicant/Proprietor

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Classified to

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